

Appl. No. 10/734,381
Atty. Docket No. 7858MRR
Amdt. Dated April 30, 2007
Reply to Final Office Action Dated November 30, 2006
Customer Number 27752

REMARKS

Claim Status

Claim 1 is amended to specifically define the present claimed phosphonate-containing copolymers or cotelomers as being substantive to teeth and providing increased hydrophilic character to teeth surfaces. Support for this amendment may be found in the Specification at Pages 6-7 in the paragraphs describing the characteristics of polymers suitable for use in the present claimed method.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Claims 1 to 6 and 10 are under consideration. Claims 7 to 9 are withdrawn.

Election of Species Requirement

Applicants confirm the election with traverse of triclosan as the single species of additional oral care agent to prosecute in the application, in response to the election of species requirement issued by the Examiner by telephone on March 3, 2006 and maintained in the current official action. Claims 7 to 9 which are drawn to nonelected species are withdrawn at this time.

Rejection Under 35 USC 112, 1st Paragraph

The Office Action states that Claims 1-6 and 10 are rejected under 35 USC § 112, 1st Paragraph, as failing to comply with the written description requirement. It is contended that the Specification does not describe the broad genus of "phosphonate group containing copolymer(s) or cotelomer(s)" recited in the claims as previously amended.

It is respectfully submitted that the claims as now amended are in full compliance of the requirements of 35 U.S.C. § 112, 1st Paragraph and the rejection should be withdrawn.

Claim 1 has been amended to specify that the claimed "phosphonate group containing copolymer(s) or cotelomer(s)" are substantive to teeth and provide increased hydrophilic character to teeth surfaces, as described in the Specification.

Claims Rejection Under 35 U.S.C. §102(b)

Claims 1-6 and 10 have been rejected under 35 USC §102(b) as being anticipated by Gaffar et al. (U.S. 5,032,386). It is contended that Gaffar discloses antiplaque dentifrices comprising (1) antiplaque agents such as triclosan, (2) polyphosphonates having affinity for tooth surfaces and (3) fluorine compounds such as sodium fluoride. Further, it is contended that since Gaffar's compositions provide a continuous film over teeth surfaces following application to

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prevent bacterial attachment to tooth surfaces, it is expected they would also provide enhanced fluoride incorporation into and remineralization of a subject's teeth.

Applicants respectfully traverse the Examiner's rejection of the claims under 35 §102(b) and submit that the claimed method to provide enhanced fluoride incorporation into and remineralization of the subject's teeth is novel from Gaffar.

It is respectfully submitted that Gaffar has no disclosure of the present claimed phosphonate containing copolymers or cotelomers that (1) are substantive to teeth., (2) provide increased hydrophilic character to teeth surfaces and (3) have the activity of enhancing fluoridation and remineralization of teeth. As demonstrated in the studies conducted by Applicants, incorporation of the present phosphonate copolymers in fluoride dentifrices results in increased fluoride uptake. Thus for example, as shown in Table 1 in the Specification, a composition with 1100 ppm fluoride and 2.5% diphosphonate/acrylate copolymer provides nearly the same fluoride uptake as a composition containing 2800 ppm fluoride and significantly greater fluoride uptake (70% increase) compared to a composition with 1100 ppm fluoride but no phosphonate polymer. The present phosphonate containing polymeric materials are also characterized by being hydrophilic and having the activity to deposit on teeth and increase hydrophilic character of teeth surfaces. By contrast, Gaffar discloses polyphosphonates, such as poly (vinyl phosphonic acid), poly (beta styrene phosphonic acid and poly (butene-4,4-diphosphonate) which are hydrophobic, rather than hydrophilic. Gaffar's polyphosphonates are intended to function as antibacterial-enhancing agent (AEA), specifically to enhance delivery of noncationic water-insoluble (i.e., hydrophobic) antibacterials such as triclosan to oral surfaces. Thus Gaffar's AEA materials necessarily contain delivery enhancing groups and retention-enhancing groups. The delivery enhancing group such as phosphonate serves to attach the AEA to the tooth surface. The retention enhancing group serves to bond or attach the noncationic antibacterial agent to the AEA and is hydrophobic. The AEA would carry with it the noncationic antibacterial agent to the tooth surface upon deposition. For example, a preferred AEA is poly (beta styrene phosphonic acid), which contains phosphonic group as the delivery enhancing group and styrene as the hydrophobic retention-enhancing group. The hydrophobic group is necessary to bond or attach the noncationic water-insoluble antibacterial agent, which is also hydrophobic. Attention is directed to the following teaching in Gaffar at Column 6 regarding the hydrophobic nature of the AEA material.

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The organic retention-enhancing group, generally hydrophobic, attaches or otherwise bonds the antibacterial agent to the AEA, thereby promoting retention of the antibacterial agent to the AEA and indirectly on the oral surfaces. In some instances, attachment of the antibacterial agent occurs through physical entrapment thereof by the AEA, especially when the AEA is a cross-linked polymer, the structure of which inherently provides increased sites for such entrapment. The presence of a higher molecular weight, more hydrophobic cross-linking moiety in the cross-linked polymer still further promotes the physical entrapment of the antibacterial agent to or by the cross-linked AEA polymer.

Gaffar also teaches that other phosphonate copolymers such as disclosed in EPO 0321233 may be employed in the referenced compositions; however, Gaffar also specifies that such copolymers must contain or be modified to contain the above-defined hydrophobic retention-enhancing agents. (See Column 8, lines 1-3 of the patent.) Polymers that contain or are modified to contain Gaffar's hydrophobic retention-enhancing groups would be hydrophobic, rather than hydrophilic.

Therefore, Gaffar has no teaching of the present hydrophilic phosphonate copolymers or cotelomers, and definitely no teaching that the referenced phosphonate polymers would even attach fluoride and deliver it to the tooth surface and thereby increase fluoridation and remineralization of teeth. The rejection under 35 USC §102(b) in view of Gaffar should be withdrawn.

Double Patenting Rejection

Claims 1-6 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-4 of commonly-assigned copending Application No. 10/737,425 in view of Gaffar et al.

In the interest of advancing prosecution of this case, Applicants will file a terminal disclaimer upon indication of allowance, which should overcome the double patenting rejection.

CONCLUSION

Applicants have made an earnest effort to place their application in proper form and to distinguish the invention as now claimed from the applied reference. In view of the foregoing, acceptance of the request for continued examination (RCE) and reconsideration of the application, entry of the amendments presented, withdrawal of the rejections under 35 U.S.C. §

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112, 1st Paragraph and §102(b), rejoining of the withdrawn claims, and allowance of all claims are respectfully requested.

The Examiner is respectfully invited to telephone the undersigned representative if it is believed an interview might be useful to advance prosecution of this case.

Respectfully submitted,

THE PROCTER & GAMBLE COMPANY

By Emelyn L. Hiland

Emelyn L. Hiland
Agent for Applicant(s)
Registration No. 41,501
(513) 622-3236

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